

**Remarks**

This Amendment is in response to the Office Action dated **September 17, 2007**.

**Claim Objection**

Claim 3 has been objected to as redundant of claim 20. Claim 3 has been cancelled.

**New Matter/Written Description**

The specification has been objected to on the basis that the amendment of July 2, 2007 added new matter in the addition of the word "liquid" before "heated fluid." Claims 17, 21 and 22 have been rejected for failure to satisfy the written description requirement of 35 USC §112, first paragraph, for the insertion of the same word. The objection and rejection are traversed.

The tests for new matter and sufficiency of written description support are the same, namely is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Company v. Far-Mar-Co., Inc.*, 227 USPQ 177 (Fed. Cir. 1985). In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* (identical language) support for the claimed subject matter at issue. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996); *In re Wright*, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989). The failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented. *All Dental Prodx*

*LLC v. Advantage Dental Products Inc.*, 64 USPQ2d 1945, 1948 (CA FC 2002). Drawings alone have been found to provide the necessary written description for a claimed invention. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991).

Written description support was identified in the amendment. The Office Action fails to address this support. The objection and rejection therefore are inadequate as a matter of law. The basis for written description support is again stated hereinbelow.

The application discloses heated water or oil as typical heating fluids at page 4, lines 29-32 and water, glycerol, mineral oil or silicone oil at page 7, lines 7-9. These are liquids. Further the application discloses that "those with relatively lower viscosities are preferred," (page 7, line 10) which a skilled person will understand to be directed to relative properties of the liquid fluids. Further the application contrasts the heating the parison by direct contact with the heating fluid with indirect transfer through the space between the mold cavity (page 7, lines 24 - page 8, line 4), a contrast that requires that the heating fluid be different from air. Consequently the skilled person clearly understands from the original disclosure that the heated fluid employed in the inventive method may be a liquid. According to the controlling case law this is sufficient to satisfy the written description requirement and consequently no new matter has been added.

There new matter objection and written description rejection are clearly unwarranted. Withdrawal is respectfully requested.

#### **Indefiniteness**

Claims 2-16 have been objected to as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Office Action contends that it is unclear how the claims "further define the methodical stepwise invention of independent claim

17." Claims 7, 8, 11, 12, 15 and 16 have been amended to resolve antecedent basis issues found in those claims. Otherwise the rejection is traversed.

The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

There is no basis in the statute or in case law to assert that dependent method claims must further define the methodical stepwise invention of the independent claim from which they depend. The method of claim 17 requires use of a mold having a certain configuration. Claims 2 and 4-16 provide additional specifications for the configuration of the mold or of particular mold features. Nothing in the rejection indicates that these additional specifications are not understandable. The rejection is not well taken. Withdrawal is requested.

### **Claim Rejections - 35 USC § 102**

Claims 17, 20, 22, 2-5, 7-9 and 13-14 have been rejected as anticipated by Leonhardt, US 5,522,961. Reconsideration is requested. Claim 17 recites that "the heated liquid fluid enters the mold cavity to directly contact the parison when the mold is immersed." This direct contact provides advantages as previously indicated. Leonhardt pertains to a balloon molding process in which a mold is immersed into a bath of water, and the mold has holes 46. However Leonhardt specifically teaches that the holes 46 "provide for the escape of *air* when the mold is filled by the expanding workpiece" (3:62-64) (emphasis added). Thus it is clear that the holes are not sized or channeled in a way that permits water to enter the cavity and contact the parison as recited in claim 17.

The Final Action contends that "water would pass through the holes 46 while the mold is submerged" in Leonhard's molding process, and that air and water will be expelled when the parison is expanded. There are several problems with this assertion. First, Leonhardt immerses for 30-35 seconds before pressurization (4:28-30) so there is plenty of time for the mold to completely fill, if the holes are of sufficient size to allow water in. Second, the bottom of the mold is on the right side of Fig. 2 (4:12-14) so if water does enter the mold there is no location of the cavity in which air would be trapped. If it comes in at all, the mold cavity will completely fill with water. There will be no air left in the mold to be expelled when the parison expands. Third, the mold is transparent (3:52-53) so Leonhardt clearly can see if water enters the mold when it is immersed and if it is expelled when the parison expands. In that context the fact that Leonhardt teaches that the holes "provide for the escape of air when the mold is filled by the expanding workpiece" can only be reasonably taken as a teaching that the holes do not permit entry of water when the mold is immersed.

Finally, the Office Action contends that attorney's arguments cannot take place of evidence in the record citing MPEP 2145. In this case, however, Leonhard itself provides the evidence in the record. Applicant has no burden to show that Leonhard operates according to its express teaching. It is the Office Action that is contending that Leonhard operates in a manner different from what it expressly teaches, and it is that contention that has no evidentiary support in the record.

Withdrawal of the anticipation rejection on Leonhardt is therefore respectfully requested.

**Claim Rejections - 35 USC § 103**

Claims 6, 10-12 and 15 -16 have been rejected for obviousness from Leonhardt, the Office Action contending that the recitations of these claims are obvious matters of design choice. The rejection suffers the same deficiency as the rejection of claim 17 and is traversed for that reason.

Further, with regard to claims 15 and 16, the size of the hole is not merely a matter of design choice. In the present invention the object is to get water into contact the parison. In Leonhardt the object is to let air out when the parison expands. These different design criteria will produce very different choices for hole size.

At least for the reasons given above withdrawal of the obviousness rejection of claims 6, 10-12 and 15 -16 on Leonhardt is requested.

Claims 18 and 21 have been rejected as obvious from Leonhardt in view of Gass-Erb. Claim 21 has been cancelled. The rejection of claim 18 suffers the same deficiency as the rejection of claim 17 and is traversed for at least that reason. Withdrawal of the rejection is requested.

Moreover, the applicant continues to disagree with the characterization of Gass-Erb. In Gass-Erb the immersed object is a heater that also performs the agitation. The Office Action asserts that the document shows agitation with an immersed object. The applicant's point is that the immersed object is the heater. It is not being heated by the fluid. The problems are not analogous. At least for this additional reason withdrawal of the rejection of claim 18 on Leonhardt in view of Gass-Erb is respectfully requested.

Claim 19 has been rejected as obvious from Leonhardt in view of Garrett. The rejection suffers the same deficiency as the rejection of claim 17 and is traversed for at least that reason. Withdrawal of the rejection is requested.

Moreover, the skilled person molding a medical device balloon would not look to a device such as disclosed in Garrett for guidance in modifying a balloon molding process. It would never happen. The process, apparatus and articles of Garrett are too different to be of any interest to the person of skill in the balloon blowing art. At least for this additional reason withdrawal of the obviousness rejection of claim 19 on Leonhardt in view of Garrett is respectfully requested.

### **Conclusion**

For the reasons given above the outstanding rejections are seen to have been overcome. The application is seen to be in condition for allowance. Early and favorable action thereon is respectfully requested.

Respectfully submitted,  
VIDAS, ARRETT & STEINKRAUS

Date: November 9, 2007

By: /Walter J. Steinkraus/  
Walter J. Steinkraus  
Registration No.: 29592

6109 Blue Circle Drive, Suite 2000  
Minnetonka, MN 55343-9185  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001